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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,361	12/15/2003	Mark L. Nelson	PAZ-178CPCN	6005
959	7590	06/06/2006	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109				CHANG, CELIA C
		ART UNIT		PAPER NUMBER
		1625		

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/737,361	NELSON ET AL.	
	Examiner Celia Chang	Art Unit 1625	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 27 March 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 16-28 and 42-45 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 16-28, 42-44 is/are rejected.

7)  Claim(s) 45 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date .

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election without traverse of Group IV wherein X is CR<sub>6</sub>R<sub>6</sub>' in the reply filed on Mar. 27, 2006 is acknowledged.

Claims 1-15, 29-41 have been canceled. Claims 16-28 and newly added 42-45 are pending.

2. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The amendment to claim 16 where R<sup>7</sup> is other than hydrogen and R<sup>7a</sup>-R<sup>7d</sup> are new matter. Please note that the original claim 16 the R<sup>7</sup> is hydrogen. On page 3-4, 9-10, generic description of formula III, the R<sup>7</sup> moiety has been described to be hydrogen. Specific compounds which may fall in formula III were described on pages 10-17. The particular compounds contains R<sup>7</sup> in addition to hydrogen, ethyl, phenyl, 4-t-butylphenyl, t-bu-aminomethyl, and dimethylamino. No where in the specification can the currently amended scope of "nitro, alkyl.....or a prodrug moiety" be found. Please note that such moieties and Markush elements i.e. W, W', R<sup>7a</sup>-R<sup>7d</sup> were not described or enabled in the specification as originally filed. No prodrugs or description of prodrug was found in the specification as originally filed. Such subject matter can not be considered within the four corners of the specification as originally filed. This is a new matter rejection. Removal of all new matter is required. In re Russmussen 211 USPQ 325.

3. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Please note that the compounds wherein does not contain aminomethyl moiety at the 9-position does not read on the base claim as now amended.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-24, 26 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Nelson et al. US 6,846,939 supplemented with CA 136:102231.

See col. 7, compound 9A and the examples of aminomethyl compounds in table 1, (for example KI, KJ, KL etc. not exhausted listing), see also RN 389139-85-9, 389140-03-8.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Draper et al. US 7,045,507, supplemented with CA 137:244598.

See compound at col. 519, let column, line 55 and 65, see also compound delineation by CAS 137:244598, RN 460073-35-2, 460073-40-9, 460073-53-4, 460073-78-3.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-28, 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson '939 or Draper '507.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Nelson '939 or Draper '507 disclosed anticipatory compounds which have been delineated supra over the base claim.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the anticipatory species of the prior art and the species of the instant claims is that the instant claims have an obvious variation of the prior art species by having an altenative chain length, or chain branches, such as RN 389139-85-9 of '939 jhas t-butyl substituted aminomethyl, while instant claim 26, p.9, 1st column, 5<sup>th</sup> compound has n-bu and 7th compound has isobu, RN 389140-03-8 has C5-ester while p.9, 1st column, compound 2-4 have variations of chain length for such ester moiety.

*Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)*

One having ordinary skill in the art in possession of the above references would be motivated to make any compounds generically taught by the prior art reference. The difference in chain length, branch or straight are within the teaching of the variations as generically disclosed with guidelines in many examples of the disclosed variation. One skilled in the art guided by the anticipatory species and the variations exemplified in the two reference would be motivated to prepared all the generically disclosed tetracycline compounds including those as now claimed.

7. Claims 1-28, 42-44 are directed to the same invention as that of US 6,846,939 or US 7,045,507 which are commonly assigned. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

For the unclaimed but disclosed subject matter of the issued patents, applicants are urged to consult MPEP 715.01 (b)-(c) for filing appropriate declarations under 37 CFR 1.132 so as to place the references under 103(c).

8. Claim 45 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



*Celia Chang  
Primary Examiner  
Art Unit 1625*

*OACS/Chang  
May 24, 2006*